Section c.) Remarks.

This reply is in response to the Office Action dated March 4, 2004.

Claims 1-3, 5, 6, 8, and 10 are pending in the application. The claims have been rejected as being unpatentable over Fabo (WO 960907) in view of Luckman (Canadian 2,101,509) under Section 103(a).

The invention relates to a method for adhering a prosthesis to a human or animal body with an adhesive device, and a prosthesis with the adhesive device adhered thereto. The improvement resides in the use of an adhesive device which is a carrier sheet having at least two surfaces. On one surface of the carrier sheet is a first, continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2. The first layer of the gel has sufficient tack to adhere to a prosthesis. On a second surface of the carrier sheet is a second continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2. The second layer of the gel has sufficient tack to adhere to a human body or to an animal body.

In contrast, Fabo fails to teach the claimed method or prothesis. Thus, nothing in Fabo teaches, suggests, anticipates, or renders obvious, a method of using a silicone gel composition to adhere a prosthesis to a human or animal body. Rather, Fabo teaches that the his compositions are used in the healthcare industry as a dressing.

As noted by the Examiner, the Board of Appeals did reject the original claims over Fabo. However the rationale behind the Board's decision was that the top sheet 4 and the protective layer 5 in the Fabo reference were substrates adhered together with the gel. The pending claims however have been limited to a prosthesis and a human or animal body. Nothing in Fabo

describes any method relating to adhering a prosthesis to a human or animal body with the gel adhesive.

While Luckman teaches a breast enhancement device adhered to the chest wall of the wearer with an adhesive, the adhesive is Dow Corning Corporation's SILASTIC® Medical Adhesive Silicone, Type A. The Examiner has taken the position that the breast prosthesis in Luckman is adhered to a human body, in the manner claimed in the present invention. In Luckman, there is no carrier sheet having two surfaces that contain a silicone gel. Instead, the device is directly adhered to the chest wall with SILASTIC® Medical Adhesive Silicone, Type A adhesive layer 14.

The Examiner will find attached hereto a Data Sheet and a Material Safety Data Sheet (MSDS) describing SILASTIC® Medical Adhesive Silicone, Type A. As is apparent from a review of the Data Sheet and the MSDS, the adhesive taught in Luckman is not a gel. Rather, it is a structural adhesive or sealant akin to a cement and glue. The composition is sticky and honey like before cure, and then forms a strong rubber with a tack free surface after cure. The cure is initiated and completed when the adhesive is brought into contact with the substrate. It is chemically bonded to the adhered surface, and is intended to provide a permanent attachment that cannot be removed without damaging the substrate.

In particular, the Examiner should note that on the first page of the Data Sheet, the SILASTIC® Medical Adhesive Silicone, Type A is described as a being a translucent paste used to permanently bond materials. On Page 2, it is said to form a tack-free outer skin a few minutes after application. On Page 7 of the MSDS, it is shown to be formed by a reaction involving a catalyst free mixture consisting of an hydroxy-terminated dimethylsiloxane, methylated silica, methyltriacetoxysilane, and ethyltriacetoxysilane. Claims 1, 8, and 10, on the other hand require

that the first and second continuous layers of silicone gel according to the invention are formed by the reaction of a silicone having Si-H groups with a silicone having Si-aliphatically unsaturated groups, and in the presence of a platinum or rhodium catalyst.

The adhesive gels in the present invention have qualities and behavior profiles akin to a pressure sensitive adhesive. In this regard, the gel adhesive-substrate interface does not resist separation when the adhesive is peeled off. Instead, because the gel has excellent wetting, spreadability, and visco-elasticity properties, it is able to quickly adhere to a surface and develop physical interactions with the surface, and not chemical interactions as in a structural adhesive. Thus, the gel can be removed without deteriorating the surface and/or leaving a residue.

Because of these differences, the gel can be characterized as being a *comfortable adhesive*, providing a soft, movable gel mass against the skin, rather than a permanent rubber cement. Moreover, because of these properties, the gel retains its tack after being removed, so it can be easily removed, moved, and reused. In addition, its unique properties allow for quick, easy, and comfortable, repositioning of medical prosthesis.

The Data Sheet on the first page indicates that during the use of the SILASTIC® Medical Adhesive Silicone, Type A, the composition releases acetic acid. It is apparent that this type of adhesive would not be suitable for uses contemplated by the present invention or uses described in Fabo. Thus, it is not considered that one skilled in the art would not seek to use an adhesive composition in a manner inconsistent with its intended use, and which could potentially be detrimental to the surface to which it is to contact, i.e., a human or animal body. In addition, and as noted above, the SILASTIC® Medical Adhesive Silicone, Type A is intended to be used to permanently bond materials, rather than provide an attachment which can be easily removed without causing damage to the underlying surface, as in the present application and as in Fabo.

Thus, it is not seen wherein it would be obvious to one skilled in the art to combine any teaching from Luckman into Fabo, or vice versa for that matter.

Since nothing in Fabo or Luckman teach or disclose the use of gel like adhesives in a method for adhering prosthesis, it is considered that the claims distinguish over the cited references for the reasons stated, and the Examiner is requested to withdraw the rejection and pass the case to issue.

Respectfully submitted,

DOW CORNING CORPORATION

Jim L. De Cesare, Reg. No. 27979, Telephone (989) 496-4235

Attachment - 11 Pages - Data Sheet & MSDS

DOW CORNING

Product Information
Healthcare

SILASTIC® Medical Adhesive Silicone, Type A
Silicone Adhesive/Sealant

FEATURES

- Cures at room temperature when exposed to atmospheric moisture
- Translucent paste
- Provided in ready-to-use containers
- Available sterile and non-sterile
- Easy to apply and use

BENEFITS

- Solvent-free

COMPOSITION

- One-component adhesive/sealant

APPLICATION

- SILASTIC Medical Adhesive Silicone, Type A is a one-component, low-slump, translucent silicone material for bonding elastomers, synthetics and metals for part fabrication and medical devices.

TYPICAL PROPERTIES

Specification writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales representative prior to writing specifications on this product.

CTM[1]	ASTM[2]	Property	Unit	Value
0176		Appearance, uncured		Translucent paste
0098		Skin-over time at 55% R.H.	minutes	7-8
022	D742	Specific gravity at 25°C (77°F)		1.06
0099	D2240	Durometer hardness, Shore A[3]		35
0137A	D412	Tensile strength[3]	MPa (psi)	3.3 (480)
0137A	D412	Elongation at break[3]	%	450

1. CTM: Corporate Test Method, copies of CTMs are available on request.
2. ASTM: American Society for Testing and Materials.
3. Mechanical properties for adhesive cured a minimum of 72 hours in air at 23°C (73°F) and 50% relative humidity.

DESCRIPTION

SILASTIC Medical Adhesive Silicone, Type A is a one-component, low-slump, translucent silicone used to permanently bond materials. It contains no solvents and cures at room temperature upon exposure to atmospheric moisture. During the curing process, the silicone adhesive releases acetic acid vapor as a by-product. After final cure, the resulting silicone elastomer possesses the appearance, texture and general composition of many conventional silicone elastomers.

HOW TO USE

Surface preparation

Surfaces to be bonded or built-up with silicone adhesive should be cleaned thoroughly with non-oily cleaners or mild soap to remove possible surface contaminants. Rinse copiously with hot water and follow with a thorough rinse using distilled water. Allow surface to dry.

How to apply

Apply SILASTIC Medical Adhesive Silicone, Type A to one of the prepared surfaces, then quickly cover with the other substrate to be bonded. Apply sufficient pressure to ensure full contact, without forcing the silicone out from between the pieces. For best results, maintain a bond thickness of at least 0.25mm.

Under ambient conditions, the adhesive forms a thin, tack-free outer skin for thick-section films within a few minutes after application. Any shaping of the uncured adhesive should be completed before the skin forms.

Cure time

Curing or vulcanization time depends on the thickness of the silicone adhesive layer, the relative humidity and the accessibility of atmospheric moisture to the curing adhesive. Cure time is extended at lower humidity levels. **Dry heat will not accelerate the cure and should not be used for at least the first 72 hours.**

A 2mm thick sheet of silicone elastomer bonded to stainless steel requires approximately 24 hours for complete vulcanization. Bond strength, however, continues to increase for several days. A 6.4mm thick sheet of silicone elastomer bonded to stainless steel under the same conditions requires 48 to 96 hours for complete vulcanization.

If the relative humidity is greater than 60% when curing, a tacky surface may occur – especially with thin films. The tackiness can be removed by exposing the surface to a dry atmosphere.

Dispersion

SILASTIC Medical Adhesive Silicone, Type A may be dispersed in moisture-free aliphatic, aromatic or halogenated hydrocarbon solvents such as hexane or toluene. DOW CORNING® Q7-9180 Silicone Fluid may also be used. To disperse, the adhesive is added to the solvent and then agitated until a homogenous dispersion is obtained. A 10% concentration of SILASTIC Medical Adhesive Silicone, Type A by weight will disperse in about 10 minutes when shaken by hand. The dispersion may be applied by brushing, dipping or spraying. A thin coat of cured silicone elastomer will result. Free films and membranes can be formed by coating the dispersion on suitable release sheets, such as polyethylene. If a release agent is needed, a one percent mild, non-oily soap solution may be used. The mild soap release agent may be removed after cure by repeated rinsing with water.

NOTE: When using any solvent, always provide adequate ventilation. When using flammable solvents, take precautions to prevent fire or explosion. Follow precautions on solvent container label.

REGULATORY STATUS

A Drug Master File (DMF) for SILASTIC Medical Adhesive Silicone, Type A is on file with the U.S. Food and Drug Administration. Customers interested in authorization to reference the file must contact Dow Corning Corporation.

IMPORTANT INFORMATION

THE USER'S ATTENTION IS IN PARTICULAR DRAWN TO THE FOLLOWING STATEMENT:

It is the User's responsibility to ensure the safety and efficacy of this material for all intended uses. While this material has passed screening tests that are applicable to products intended for implantation for up to 29 days, Dow Corning makes no end-use representation based on such testing. Nor does Dow Corning make any representation concerning the suitability of this product for applications of greater than 29 days of implantation in the human body.

HANDLING PRECAUTIONS

Product safety information required for safe use is not included. Before handling, read product and safety data sheets and container labels for safe use, physical and health hazard information. The material safety data sheet is available on the Dow Corning website at www.dowcorning.com. You can also obtain a copy from your local Dow Corning sales representative or Distributor or by calling your local Dow Corning Global Connection.

USABLE LIFE AND STORAGE

When stored at or below 32°C (90°F) in the original unopened containers, this product has a usable life of 24 months from the date of production.

Because the adhesive cures upon exposure to atmospheric moisture, tubes of SILASTIC Medical Adhesive Silicone, Type A must be kept tightly closed when not in use. A plug of cured material may form in the tip of the tube or cartridge during storage. The plug is easily removed and does not affect the remaining contents.

PACKAGING

This product is available in 6 gram and 57 gram squeeze tubes, 340 gram cartridges and 18 kilogram pails.

The SILASTIC Medical Adhesive Silicone, Type A supplied in the 6 gram tube is pre-sterilized. This tube size is for single use only. Once opened, resterilization of the tube and its uncured contents is not recommended. The exterior of the tube and cap are non-sterile. They must be sterilized in a secondary packaging operation using either gamma irradiation or ethylene oxide to maintain product sterility during opening the tube. If irradiation is used, it is the user's responsibility to evaluate the effects of sterilization on the physical properties and usable life of the adhesive. If ethylene oxide sterilization is used, the gas will not penetrate the adhesive tube and will have no effect on the contents. It is the user's responsibility to validate either sterilization method to ensure sterility of the exterior and cap. DRY HEAT OR STEAM STERILIZATION MUST NOT BE USED AS THEY WILL MELT THE CAP.

The tubes used to supply the 6 gram quantities of sterile SILASTIC Medical Adhesive Silicone, Type A have blind ends. Once sterilized, only the cap supplied with the adhesive should be used to open the blind end tube. Using the piercing pin side of the cap, push the pin straight into the tube. Remove the pin/cap and dispense the amount of adhesive desired. TO AVOID CONTAMINATION, USE ONLY THE CAP PROVIDED WITH THE ADHESIVE AND PUSH THE PIERCING PIN STRAIGHT IN.

The SILASTIC Medical Adhesive Silicone, Type A supplied in sizes other than the 6 gram tube is non-sterile in non-sterile packaging.

QUALIFICATION TESTING

The results of selected qualification tests are shown in Table 1. A summary of health data is available upon request.

ORDERING AND PRODUCT INFORMATION

For ordering and product information, contact your local Dow Corning Global Connection.

QUALITY ASSURANCE

SILASTIC Medical Adhesive Silicone, Type A is manufactured using appropriate principles of current Good Manufacturing Practice (cGMP). The Dow Corning Healthcare Industries Materials Site (HIMS) in Hemlock, MI, is dedicated to the production of silicone materials for healthcare applications. It is registered with the FDA (CFN 1816403) as a Drug Establishment. Dow Corning is globally registered to the ISO 9001 Quality Standard. Registration certificate number FM 10734 has been obtained through the British Standards Institution (BSI). Certification to ISO 9001 through an independent third party indicates that Dow Corning operates a quality management system in accordance with the standard, ensuring full documentation and traceability.

HEALTH AND ENVIRONMENTAL INFORMATION

To support Customers in their product safety needs, Dow Corning has an extensive Product Stewardship organization and a team of Product Safety and Regulatory Compliance (PS&RC) specialists available in each area.

For further information, please see our website, www.dowcorning.com or consult your local Dow Corning representative.

LIMITED WARRANTY INFORMATION - PLEASE READ CAREFULLY

The information contained herein is offered in good faith and is believed to be accurate. However, because conditions and methods of use of our products are beyond our control, this information should not be used in substitution for customers' tests to ensure that Dow Corning's products are safe, effective, and fully satisfactory for the intended end use. Suggestions of use shall not be taken as inducements to infringe any patent.

Dow Corning's sole warranty is that the product will meet the Dow Corning sales specifications in effect at the time of shipment.

Your exclusive remedy for breach of such warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted.

DOW CORNING SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY.

DOW CORNING DISCLAIMS LIABILITY FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

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www.dowcorning.com

Table 1: Selected Qualification Data for SILASTIC Medical Adhesive Silicone, Type A[1]

Test	*Samples tested*	*Summary result*
Cell culture[2]	Cured adhesive	No cytopathic effect
	Cell culture medium extract of cured adhesive	No cytopathic effect
USP Pyrogen	Saline extract of cured adhesive	Non-pyrogenic
Skin sensitization[3]	• Cured adhesive • Saline extract of cured adhesive • Acetone extract of cured adhesive	No sensitization
Mutagenicity	• Acetone extract of cured adhesive • Saline extract of cured adhesive	No evidence of genetic activity or cytotoxicity in the bacterial reverse mutation assay
USP Class V • Systemic toxicity • Intracutaneous reactivity[3]	• Saline extract of cured adhesive • Extract of cured adhesive in 5% ethanol/95% saline • PEG 400 extract of cured adhesive • Cottonseed oil extract of cured adhesive	Non-irritating and non-toxic relative to controls
Implant	Cured adhesive	Reaction equivalent to or less than negative control at 7, 30 and 90-days post-implantation

1. Prior to testing, cured adhesive was sterilized at 120°C (250°F) for 20 minutes at 15psi.
2. Prior to sterilization, cured adhesive was heat-treated at 200°C (392°F) for 15 minutes in an open dish to eliminate acetic acid generated during cure.
3. Tests meet ISO 10993-1 requirements for Surface Devices with "limited" (<24 hours) or "prolonged" (1 to 30 days) contact duration.

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DOW CORNING CORPORATION
Material Safety Data Sheet

SILASTIC(R) MEDICAL ADHESIVE SILICONE, TYPE A

1. IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

Dow Corning Corporation
South Saginaw Road
Midland, Michigan 48686

24 Hour Emergency Telephone: (989) 496-5900
Customer Service: (989) 496-6000
Product Disposal Information: (989) 496-6315
CHEMTREC: (800) 424-9300

MSDS No.: 01019821

Revision Date: 2001/10/16

Generic Description: Silicone compound
Physical Form: Paste
Color: Translucent white
Odor: Acetic acid odor

NFPA Profile: Health 2 Flammability 1 Instability/Reactivity 0

Note: NFPA = National Fire Protection Association

2. OSHA HAZARDOUS COMPONENTS

CAS Number	Wt %	Component Name
4253-34-3	3.0 - 7.0	Methyltriacetoxysilane
17689-77-9	3.0 - 7.0	Ethyltriacetoxysilane

The above components are hazardous as defined in 29 CFR 1910.1200.

3. EFFECTS OF OVEREXPOSURE

Acute Effects

Eye: Direct contact may cause moderate irritation.

Skin: May cause moderate irritation.

Inhalation: Irritates respiratory passages very slightly.

Oral: Low ingestion hazard in normal use.

Prolonged/Repeated Exposure Effects

Skin: No known applicable information.

Inhalation: No known applicable information.

Oral: No known applicable information.

Signs and Symptoms of Overexposure

No known applicable information.

Medical Conditions Aggravated by Exposure

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SILASTIC(R) MEDICAL ADHESIVE SILICONE, TYPE A

No known applicable information.

The above listed potential effects of overexposure are based on actual data, results of studies performed upon similar compositions, component data and/or expert review of the product. Please refer to Section 11 for the detailed toxicology information.

4. FIRST AID MEASURES

Eye:	Immediately flush with water for 15 minutes. Get medical attention.
Skin:	Remove from skin and wash thoroughly with soap and water or waterless cleanser. Get medical attention if irritation or other ill effects develop or persist.
Inhalation:	No first aid should be needed.
Oral:	No first aid should be needed.
Comments:	Treat according to person's condition and specifics of exposure.

5. FIRE FIGHTING MEASURES

Flash Point:	Not applicable - Solid
Autoignition Temperature:	Not determined.
Flammability Limits in Air:	Not determined.
Extinguishing Media:	On large fires use dry chemical, foam or water spray. On small fires use carbon dioxide (CO2), dry chemical or water spray. Water can be used to cool fire exposed containers.
Fire Fighting Measures:	Self-contained breathing apparatus and protective clothing should be worn in fighting large fires involving chemicals. Use water spray to keep fire exposed containers cool.
Unusual Fire Hazards:	None.

Hazardous Decomposition Products

Thermal breakdown of this product during fire or very high heat conditions may evolve the following hazardous decomposition products: Carbon oxides and traces of incompletely burned carbon compounds. Silicon dioxide. Chlorine compounds. Metal oxides. Formaldehyde.

6. ACCIDENTAL RELEASE MEASURES

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Material Safety Data Sheet

SILASTIC(R) MEDICAL ADHESIVE SILICONE, TYPE A

Containment/Clean up: Observe all personal protection equipment recommendations described in Sections 5 and 8. Clean area as appropriate since some silicone materials, even in small quantities, may present a slip hazard. Final cleaning may require use of steam, solvents or detergents. Dispose of saturated absorbant or cleaning materials appropriately, since spontaneous heating may occur. Local, state and federal laws and regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which federal, state and local laws and regulations are applicable. Sections 13 and 15 of this MSDS provide information regarding certain federal and state requirements.

Note: See section 8 for Personal Protective Equipment for Spills. Call Dow Corning Corporation, (989) 496-5900, if additional information is required.

7. HANDLING AND STORAGE

Use with adequate ventilation. Product evolves acetic acid (HOAc) when exposed to water or humid air. Provide ventilation during use to control HOAc within exposure guidelines or use respiratory protection. Avoid eye contact. Avoid skin contact.

Use reasonable care and store away from oxidizing materials. Keep container closed and store away from water or moisture.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Component Exposure Limits

CAS Number	Component Name	Exposure Limits
4253-34-3	Methyltriacetoxysilane	See acetic acid comments.
17689-77-9	Ethyltriacetoxysilane	See acetic acid comments.

Acetic acid is formed upon contact with water or humid air. Provide adequate ventilation to control exposures within guidelines of OSHA PEL: TWA 10 ppm and ACGIH TLV: TWA 10 ppm, STEL 15 ppm.

Engineering Controls

Local Ventilation: Recommended.
General Ventilation: Recommended.

Personal Protective Equipment for Routine Handling

Eyes: Use proper protection - safety glasses as a minimum.

Skin: Wash at mealtime and end of shift. Contaminated clothing and shoes should be removed as soon as practical and thoroughly cleaned before reuse. Chemical protective gloves are recommended.

Suitable Gloves: Nitrile Rubber. Neoprene Rubber(R). Butyl Rubber. 4H(R). Polyvinylchloride.

Inhalation: No respiratory protection should be needed.

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SILASTIC(R) MEDICAL ADHESIVE SILICONE, TYPE A

Suitable Respirator:	None should be needed.

Personal Protective Equipment for Spills

Eyes:	Use proper protection - safety glasses as a minimum.
Skin:	Wash at mealtime and end of shift. Contaminated clothing and shoes should be removed as soon as practical and thoroughly cleaned before reuse. Chemical protective gloves are recommended.
Inhalation/Suitable Respirator:	No respiratory protection should be needed.
Precautionary Measures:	Avoid eye contact. Avoid skin contact. Use reasonable care.
Comments:	Product evolves acetic acid (HOAc) when exposed to water or humid air. Provide ventilation during use to control HOAc within exposure guidelines or use respiratory protection.
	When heated to temperatures above 150 degrees C in the presence of air, product can form formaldehyde vapors. Formaldehyde is a potential cancer hazard, a known skin and respiratory sensitizer, and an irritant to the eyes, nose, throat, skin, and digestive system. Safe handling conditions may be maintained by keeping vapor concentrations within the OSHA Permissible Exposure Limit for formaldehyde.

Note: These precautions are for room temperature handling. Use at elevated temperature or aerosol/spray applications may require added precautions.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Form:	Paste
Color:	Translucent white
Odor:	Acetic acid odor
Specific Gravity @ 25°C:	1.06
Viscosity:	Not determined.
Freezing/Melting Point:	Not determined.
Boiling Point:	Not determined.
Vapor Pressure @ 25°C:	Not determined.
Vapor Density:	Not determined.
Solubility in Water:	Not determined.
pH:	Not determined.
Volatile Content:	Not determined.

Note: The above information is not intended for use in preparing product specifications. Contact Dow Corning before writing specifications.

10. STABILITY AND REACTIVITY

Chemical Stability:	Stable.
Hazardous Polymerization:	Hazardous polymerization will not occur.

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Material Safety Data Sheet

SILASTIC(R) MEDICAL ADHESIVE SILICONE, TYPE A

Conditions to Avoid: None.

Materials to Avoid: Oxidizing material can cause a reaction. Water, moisture, or humid air can cause hazardous vapors to form as described in Section 8.

11. TOXICOLOGICAL INFORMATION

Special Hazard Information on Components

No known applicable information.

12. ECOLOGICAL INFORMATION

Environmental Fate and Distribution

Complete information is not yet available.

Environmental Effects

Complete information is not yet available.

Fate and Effects in Waste Water Treatment Plants

Complete information is not yet available.

Ecotoxicity Classification Criteria

Hazard Parameters (LC50 or EC50)	High	Medium	Low
Acute Aquatic Toxicity (mg/L)	<=1	>1 and <=100	>100
Acute Terrestrial Toxicity	<=100	>100 and <= 2000	>2000

This table is adapted from "Environmental Toxicology and Risk Assessment", ASTM STP 1179, p.34, 1993.

This table can be used to classify the ecotoxicity of this product when ecotoxicity data is listed above. Please read the other information presented in the section concerning the overall ecological safety of this material.

13. DISPOSAL CONSIDERATIONS

RCRA Hazard Class (40 CFR 261)

When a decision is made to discard this material, as received, is it classified as a hazardous waste? No

State or local laws may impose additional regulatory requirements regarding disposal.

Call Dow Corning Corporate Environmental Management, (989) 496-6315, if additional information is required.

14. TRANSPORT INFORMATION

DOT Road Shipment Information (49 CFR 172.101)

Not subject to DOT.

Ocean Shipment (IMDG)

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Not subject to IMDG code.

Air Shipment (IATA)

Not subject to IATA regulations.

Call Dow Corning Transportation, (989) 496-8577, if additional information is required.

15. REGULATORY INFORMATION

Contents of this MSDS comply with the OSHA Hazard Communication Standard 29 CFR 1910.1200.

TSCA Status: All chemical substances in this material are included on or exempted from listing on the TSCA Inventory of Chemical Substances.

EPA SARA Title III Chemical Listings

Section 302 Extremely Hazardous Substances:

None.

Section 304 CERCLA Hazardous Substances:

None.

Section 312 Hazard Class:

Acute: Yes
Chronic: No
Fire: No
Pressure: No
Reactive: No

Section 313 Toxic Chemicals:

None present or none present in regulated quantities.

Supplemental State Compliance Information

California

Warning: This product contains the following chemical(s) listed by the State of California under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) as being known to cause cancer, birth defects or other reproductive harm.

None known.

Massachusetts

No ingredient regulated by MA Right-to-Know Law present.

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Material Safety Data Sheet

SILASTIC(R) MEDICAL ADHESIVE SILICONE, TYPE A

New Jersey

CAS Number	Wt %	Component Name
70131-67-8	> 60.0	Dimethyl siloxane, hydroxy-terminated
68611-44-9	10.0 - 30.0	Methylated silica
4253-34-3	3.0 - 7.0	Methyltriacetoxysilane
17689-77-9	3.0 - 7.0	Ethyltriacetoxysilane

Pennsylvania

CAS Number	Wt %	Component Name
70131-67-8	> 60.0	Dimethyl siloxane, hydroxy-terminated
68611-44-9	10.0 - 30.0	Methylated silica
4253-34-3	3.0 - 7.0	Methyltriacetoxysilane
17689-77-9	3.0 - 7.0	Ethyltriacetoxysilane

16. OTHER INFORMATION

Prepared by: Dow Corning Corporation

These data are offered in good faith as typical values and not as product specifications. No warranty, either expressed or implied, is hereby made. The recommended industrial hygiene and safe handling procedures are believed to be generally applicable. However, each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.

(R) indicates Registered Trademark